UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DELAWARE HEALTH CORPORATION, a Delaware corporation Plaintiff, v. MICHAEL O. LEAVITT, Secretary of Health and Human Services, Defendant.	)	Case Number: 07-829-SLR

OPENING BRIEF IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

COLM F. CONNOLLY
United States Attorney

By: Lesley F. Wolf
Assistant United States Attorney
1007 N. Orange Street, Suite 700
Wilmington, Delaware 19801
(302) 573-6277

Brett J. Bierer
Attorney
U.S. Department of Health and Human Services
Office of the General Counsel
CMS Division
Room C2-05-23
7500 Security Boulevard
Baltimore, Maryland 21244–1850
(410) 786-1473

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INTRODUCTION

Plaintiff Delaware Health Corporation, a.k.a. Harbor Healthcare & Rehabilitation Center, ("Delaware Health" or "Provider") operates a skilled nursing facility ("SNF") that participates in the Medicare program. It filed this action to contest the final decision of the Secretary of Health and Human Services ("the Secretary") reducing the amount of Medicare reimbursement Plaintiff received for furnishing occupational and speech therapy services to Medicare beneficiaries during Plaintiff's fiscal years ending December 31, 1996 and December 31, 1997. As explained more fully herein, the Secretary's decision to reduce Plaintiff's payments was fully consistent with governing law and was necessary to account for fraudulent billing by one of Plaintiff's SNF's sub-contractors. Medicare providers such as Plaintiff's SNF are required to provide auditable documentation to support their billings. Here, the provider was unable to substantiate its Medicare claims for the fraudulent hours billed, and was thus not entitled to any of the reimbursement the Secretary removed. As a result, there is substantial evidence in the record taken as a whole to support the Secretary's actions in this case, and the Court should affirm the Secretary's adjustments to Plaintiff's Medicare reimbursement.

BACKGROUND

I. Statutory and Regulatory Background

A. Medicare Program Overview

The Medicare program was established by Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395, et seq., to help finance health care services and products for elderly

and disabled persons. The program is divided into two parts relevant to this case, which are commonly referred to as "Part A" and "Part B." Medicare Part A provides certain benefits covering institutional care such as inpatient hospital, nursing facility, and home health and hospice care. 42 U.S.C. §§ 1395c-1395i-2. Medicare Part B provides benefits for such areas as outpatient hospital visits, physician services, durable medical equipment and diagnostic tests, and other types of outpatient services. 42 U.S.C. § 1395k.

Under Medicare Part A, service providers such as SNFs enter into "provider agreements" with the Secretary. 42 U.S.C. § 1395cc. During the periods at issue in this case, the Secretary, acting through contractors known as fiscal intermediaries ("the Intermediary"), paid SNFs the "reasonable cost" of covered services they furnished to Medicare beneficiaries. 42 U.S.C. §§ 1395f(b)(1), 1395h. One of the items of a health care provider's costs that the Medicare program recognizes as a reasonable cost is the cost of furnishing physical, occupational, and speech therapy services "under arrangement," that is, the provider's cost of purchasing such services for its patients from an outside vendor or sub-contractor. See 42 U.S.C. § 1395x(w); 42 C.F.R. 413.106(a). The Medicare program will reimburse such costs up to the level of certain statutorily mandated limits. Id.

Before a provider can be paid for the reasonable cost of covered services, it must furnish the Secretary with such information as he may request to determine the amount due a provider. 42 U.S.C. § 1395g(a). The Secretary has promulgated regulations establishing "principles of reasonable cost reimbursement" which require providers to maintain financial records and statistical data that can be used to accurately determine costs payable under the program. 42 C.F.R. § 413.20(a). Providers receiving payment on the basis of reimbursable cost must provide

this cost data to the Secretary (through the fiscal Intermediary), and the data must be capable of verification by qualified auditors. 42 C.F.R. § 413.24(a).

Actual costs of services cannot be determined until the end of a given cost year, so providers receive estimated payments at least monthly in the course of the cost year. Adjustments are made for any underpayment or overpayment after completion of the cost year, at which time the providers must submit annual cost reports to the Intermediary. 42 U.S.C. §§ 1395g, 1395x(v)(l)(A)(ii); 42 C.F.R. §§ 413. 64(b), 413.20(b). The Intermediary then determines the provider's reimbursable costs for services based upon its review of the annual cost report submitted by the provider. The provider is notified of the Intermediary's determination in a document known as a Notice of Program Reimbursement ("NPR"). 42 C.F.R. § 405.1803.

B. Medicare Provider Appeals

If the provider is dissatisfied with the intermediary's reimbursement determination stated in the NPR, it may appeal that decision to the Provider Reimbursement Review Board ("PRRB") if the amount in controversy is $10,000 or more, and if the request for review is submitted within 180 days of the date that the NPR was mailed to the provider. 42 U.S.C. § 1395oo; 42 C.F.R. §§ 405.1835(a), 405.1841(a). The decision of the PRRB is final unless the Administrator of the Centers for Medicare and Medicaid Services ("CMS")[1] reverses, affirms, or modifies it. 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. § 405.1877. Thereafter, a provider may seek judicial review of the Secretary's final decision in district court pursuant to the deferential standard of review contained in the Administrative Procedure Act ("APA"), 5 U.S.C. § 701-706. Id.; see 42 U.S.C. § 1395oo(f)(1).

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[1]CMS was formerly know as the Health Care Financing Administration or "HCFA."

II. Factual Background

Delaware Health operates a SNF in Lewes, Delaware, and participates as a provider in the Medicare Program. Delaware Health contracted with Whitehorse Rehabilitation Services, Inc. ("Whitehorse") to provide necessary speech and occupational therapy services to its residents for its fiscal years ending December 31, 1996 and December 31, 1997 ("FY '96 and '97"). Delaware Health submitted claims to Medicare for expenditures to Whitehorse based on Whitehorse's billings.

Whitehorse employees would provide therapy services to Delaware Health's residents, and the employees recorded units of time in 15 minute increments on monthly logs. Administrative Record ("A.R.") 77-78, 157 ¶ 2. The owner or manager Whitehorse would then either direct employees to alter the logs increasing the amount of units of services or creating new logs with increased units, or make the alterations themselves. A.R. 157-58 ¶¶ 3 and 4, 159 ¶ 6(a) and (b). The owner or manager of Whitehorse would prepare invoices or bills and send them to Delaware Health for payment. A.R. 157 ¶ 2. Whitehorse's invoices and bills to the SNFs would be based upon the altered, inflated logs. A.R. 158 ¶ 5, 159 ¶6(c).

Delaware Health received therapy bills from Whitehorse at the end of each month. A.R. 77. The bill would identify a service, the total number of units for the month, and a dollar amount. A.R. 77. Whitehorse would not break down its bills to Delaware Health based upon date of service or patient. A.R. 77. Whitehorse provided therapy logs to Delaware Health. AR. 77-78. Delaware Health also obtained a calendar at the end of the month providing the patient's name, but not the length of any therapy provided. A.R. 77. Delaware Health reconciled Whitehorse's bills with the logs, but did not reconcile them with any patient notes. A.R. 85.

Delaware Health's nursing notes would indicate that therapy was provided on a particular date, but would not indicate the length of any therapy. A.R. 79. If Whitehorse were to fraudulently increase the number of units, Delaware Health would not check to verify the number of units. A.R. 85-86. Delaware Health had no way to verify the length of time of any of Whitehorse's therapy based on records. A.R. 80-81, 87. At some point, Delaware Health began to suspect that Whitehorse engaged in improper billing, because the bills appeared higher than they should be based on the number of patients receiving therapy. A.R. 82, 88. Due to these suspicions, Delaware Health withheld partial payment. A.R. 82.

Delaware Health sought reimbursement for Whitehorse's billings by submitting claims on its annual cost reports for FY '96 and '97, and Medicare paid these claims, issuing an original notice of program reimbursement ("NPR") on September 28, 1999. A.R. 115, 118.

Subsequently, an investigation by the U.S. Attorney's Office for the District of Delaware led to the successful prosecution of two principles in Whitehorse for fraudulently billing for therapy services. A.R. 157-63. The prosecution also resulted in an order of restitution in the amount of $51,637.14 as to one defendant and $436,693.37 against the other defendant. A.R. 161, 162. The investigation revealed that Whitehorse engaged in the same fraudulent overbilling at all of the SNFs for which it provided therapy services. A.R. 140, 157-58. Subsequently, HHS's Office of Inspector General advised the Intermediary to reopen the NPRs for all of the SNFs that Whitehorse had billed and to recover the fraudulent overpayments, and provided a statistical analysis and an extrapolation of the fraudulent payments. A.R. 133-38. On August 21, 2002, in a letter captioned "Reopening of the 1996 and 1997 cost reports for Medicare purposes," the Intermediary sent a notice advising Delaware Health that the fraud had

occurred, that the Intermediary would be proposing adjustments to the NPR, and would be issuing a revised NPR. A.R. 118. That notice explicitly declared "The Office of Inspector General (OIG) has informed Empire Medicare Services (EMS)-Audit & Reimbursement Department that a reopening of the 1996 and 1997 cost reports are [sic] necessary." A.R. 118. The OIG initially advised that the Intermediary needed to reopen to recover an overpayment. A.R. 133. Subsequently, the Intermediary learned that the U.S. Attorney's office conducted an audit and the recovery was necessary due to inflated costs as a result of altered logs by the therapy provider Whitehorse. A.R. 120, 140. The Intermediary advised Delaware Health of the basis for the reopenings, provided a schedule prepared by the U.S. Attorney's Office estimating the fraudulent overpayments to Delaware Health, allowed Delaware Health to respond, and offered to review documentation from Delaware Health to support its speech and occupational therapy billings prior to issuing a revised NPR. A.R. 120-24, 148, 150. Not having received any documentation from the provider to substantiate the hours estimated to have been fraudulently billed, the Intermediary issued the revised NPR with the proposed adjustments on October 23, 2003. A.R. 126, 148. The Intermediary used the statistical extrapolation received from the OIG to remove a portion of the hours estimated to be fraudulently billed. The statistic was based upon the proportion of actual fraudulent billings Whitehorse made to one of the facilities for one month's worth of billings. A.R. 140. The U.S. Attorney's Office's investigation revealed that Whitehorse's conduct occurred at all of the facilities it serviced. A.R. 140.

Delaware Health, although it submitted no documentation to support the hours of therapy it billed and received reimbursement from Medicare, challenged its revised NPR and sought an

evidentiary hearing before the PRRB. The PRRB reversed the Intermediary.[2] The CMS Deputy Administrator, acting on authority delegated by the Administrator, reviewed the PRRB decision and reversed it, finding that the Intermediary's utilization of the extrapolated statistic was a valid method to recover for the fraudulent billings. A.R. 2-8. That decision constitutes final agency action subject to judicial review pursuant to the APA.

ARGUMENT

I. The Standard of Review is Narrow and Deferential

Jurisdiction over this action is based exclusively on 42 U.S.C. § 1395oo(f)(1), which provides for judicial review of final agency decisions on Medicare provider reimbursement disputes under the terms of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. Memorial Hosp./Adair County Health Ctr., Inc. v. Bowen, 829 F.2d 111, 116-17 (D.C. Cir. 1987). The APA standard of review, 5 U.S.C. § 706(2)(A), (E), provides that agency action, findings, and conclusions can be set aside only if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "unsupported by substantial evidence." Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 413-15 (1971); Adair County, 829 F.2d at 116-17; West Virginia v. Thompson, 475 F.3d 204, 209 (4th Cir. 2007); National Res. Defense Council, Inc. V. Environmental Prot. Agency, 16 F.3d 1395, 1400 (4th Cir. 1993); Maryland Dep't of Human Res. v. U.S. Dep't of Agric., 976 F.2d 1462, 1475 (4th Cir. 1992).

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[2]The hearing before the PRRB was nearly a sham as, like the Queen of Hearts in Alice in Wonderland, the verdict was announced before the trial began. See A.R. 74. Delaware Health sought a postponement of the proceeding (A.R. 73), but the PRRB, after consulting with each other, and before any witnesses, evidence, or even opening statements were presented, announced that it would postpone the case if Delaware Health wish to, but that the PRRB was "prepared to make a Decision now ... in favor of the Provider." A.R. 74.

The courts have consistently held that the APA establishes a narrow standard of review. Under the arbitrary and capricious standard, an agency action may be invalidated only if it is "not rational and based on consideration of the relevant factors." FCC v. National Citizens Comm. For Broadcasting, 436 U.S. 775, 803 (1978); see also Motor Vehicle Mfr. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

Review under the substantial evidence standard is similarly narrow. The Supreme Court has "defined 'substantial evidence' as 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" Consolo v. Federal Maritime Comm'n, 383 U.S. 607, 619-20 (1966), quoting Consolidated Edison Co. of New York v. NLRB, 305 U.S. 197, 229 (1938). Substantial evidence is "something less than the weight of the evidence, and the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's findings from being supported by substantial evidence." Id. at 620 (citations omitted). In applying the substantial evidence standard, the reviewing court, may not "displace the ... [Secretary's] choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it de novo." Universal Camera Corp. v. NLRB, 340 U.S. 474, 488 (1951); Shanty Town Associates, Ltd. P'ship v. Environmental Prot. Agency, 843 F.2d 782, 794 (4th Cir. 1988).

Given the narrowness of the APA standard of review, the reviewing court may not substitute its judgment for that of the agency. Rather, the agency's decision should be given deference. American Med. Int'l, Inc. v. Secretary of HEW, 466 F.Supp. 605, 611 (D.D.C. 1979), aff'd, 677 F.2d 118 (D.C. Cir. 1981). The Secretary's interpretation of his rules is entitled to controlling weight, "unless an alternative reading is compelled by the regulation's plain language

or other indications of the Secretary's intent at the time of the regulation's promulgation." Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (internal quotation marks and citation omitted.); see also Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87 (1995). Broad deference to the Secretary's interpretation of his own regulations is "all the more warranted when, as here, the regulation concerns a 'complex and highly technical regulatory program.'" Thomas Jefferson, 512 U.S. at 512, citing Pauley v. Beth Energy Mines, Inc., 501 U.S. 680, 697 (1991).

II. The Secretary Retains Vast Discretion in Applying the Reasonable Cost Principles and the Secretary's Rules are Entitled to Significant Deference

Courts have long recognized that the Secretary has "broad discretion to develop the 'reasonable cost' [reimbursement] concept ... enunciated in 42 U.S.C. § 1395x(v)(1)(A)." Richey Manor, Inc. v. Schweiker, 684 F.2d 130, 134 (D.C. Cir. 1982); see also Lexington County Hosp. v. Schweiker, 740 F.2d 287, 290 (4th Cir. 1984); Mercy Hosp. Of Laredo v. Heckler, 777 F.2d 1028, 1034 (5th Cir. 1985); Sun Towers, Inc. v. Heckler, 725 F.2d 315, 325 (5th Cir.), cert. denied, 469 U.S. 823 (1984); Fallston Gen. Hosp. v. Harris, 481 F.Supp. 1066, 1067 (D.Md. 1979); see Mercy Home Health v. Leavitt, 436 F.3d 370, 372 (3d Cir. 2006). As discussed herein, the Secretary has exercised this discretion of promulgating regulations and manual provisions that develop the reasonable cost reimbursement concept.

Section 1395x(v)(1)(A) defines "reasonable cost" as "costs 'actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services' as 'determined in accordance with regulations' promulgated by the Secretary." Biloxi Reg'l Med. Ctr. V. Bowen, 835 F.2d 345, 349 (D.C. Cir. 1987); see also Palms of

Pasadena Hosp. V. Sullivan, 932 F.2d 982, 983-84 (D.C. Cir. 1991). Thus, the Secretary's reasonable cost regulations provide for reimbursement of specific costs actually incurred by a provider if the costs are allowable, properly apportioned between Medicare and non-Medicare patients and not in excess of amounts prescribed under limiting statutory and regulatory provisions.

III. The Intermediary Properly Re-Opened the NPR in Accordance with Medicare Regulations.

Medicare regulations provide ample authority under which an Intermediary may re-open an NPR. See 42 C.F.R. § 405.1885; Provider Reimbursement Manual ("PRM") (CMS Pub. 15-1) § 2931.1; A.R. 130. The Secretary's re-opening in this case is proper: 42 C.F.R. § 405.1885(a) and (e); PRM § 2931.1A and F; A.R. 130. First, the Intermediary notified Delaware Health that it intended to reopen the case within the three years pursuant to PRM § 2931.1A. 42 C.F.R. § 405.1885(a). That notification by the Intermediary of its intention to reopen the NPR on August 21, 2002 (A.R. 118), within 3 years of the date of the original NPR, was sufficient. Additionally, pursuant to PRM § 2931.1F, there is no time limit on reopening if, as in this case, the NPR resulted from fraud.[3] 42 C.F.R. § 405.1885(e). The Intermediary Manual (CMS Pub. 13-3) §§ 3799.4 and 3799.10 reiterate that a determination may be reopened at any time if it was procured by fraud.[4] A.R. 203, 205. Thus, under either of these bases, the Secretary's reopening

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[3]The adjustment report completed by the intermediary indicates that the basis for the adjustments were "[t]o properly offset a portion of costs ... because of the existence of either fraud, the wilful misrepresentation of such costs or an overpayment in these cost centers." A.R. 135-36.

[4]The Medicare Intermediary Manual permits an unrestricted reopening of a determination if the fraud was committed by a provider or "any other person." CMS Pub. 13-3 § 3799.10A; A.R. 205. "Fraud or Similar Fault" includes: "deception by a person who knows that the

was proper.[5]

IV. The Intermediary's Use of the Statistical Extrapolation to Adjust the Cost Reports for Fraudulent Billings by Provider's Sub-Contractor Was Proper.

A. The Intermediary Had an Obligation to Adjust a Cost Report That Included Fraudulent Costs.

Medicare only reimburses for health-related services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). In order to receive reimbursement for health-related services, a provider must "furnish[ ] such information as may be necessary in order to determine the amounts due such provider ..." 42 U.S.C. § 1395l(e). Skilled nursing facilities, for the years at issue here, were reimbursed based upon their reasonable, Medicare-allowable costs, which is defined as only those costs actually incurred and necessary in the efficient delivery of needed health services. 42 U.S.C. § 1395x(v)(1)(A). Providers reimbursed based upon reasonable cost must maintain sufficient financial records and statistical data to properly account for costs, have "an adequate ongoing system for furnishing the records needed to provide accurate cost data and other information capable of verification by qualified auditors," and must furnish information to the intermediary to assure proper payments by Medicare. 42 C.F.R. § 413.20(a), (c)(1), and (d)(1). Providers must maintain sufficiently detailed information in their records to support payments made for services furnished to beneficiaries. 42 C.F.R. § 413.24(c). The records must

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deception may result in unauthorized benefits to someone;" and "[t]he submittal of incorrect, incomplete or misleading information that results in payment for ... services that were not furnished ..." Id.

[5]In addition, by regulation the Intermediary must recover any overpayment. See 42 C.F.R. § 405.371(a). The Intermediary cited that regulation as the basis for the recovery of the overpayment in this case. A.R. 135-36.

be such that are capable of verification by a qualified auditor. 42 C.F.R. § 413.24(a). The Provider must furnish sufficient information to the intermediary to determine whether payment is due and in what amount. 42 C.F.R. § 424.5(a)(6).

For the years at issue, Delaware Health outsourced its occupational and speech therapy for its SNF residents to Whitehorse Rehabilitation Services, Inc. ("Whitehorse"). A.R. 83 Delaware Health would receive bills from Whitehorse for these therapies, pay the bills and then claim Medicare reimbursement for the bills paid on the cost report. Based on the foregoing authorities, the intermediary clearly was obliged to adjust Plaintiff's cost reports when it became aware that a significant portion of Plaintiff's billings for therapy services had been based on fraud by Whitehorse. As shown below, the method the intermediary used to make that adjustment was completely lawful.

B. The Most Reasonable, and Authorized, Method to Adjust for the Inflated Costs is Use of a Statistical Extrapolation.

Under the particular facts of this case, where a healthcare provider claims that it maintains no records which could assist an intermediary in uncovering the extent of the fraudulent billing it submitted for Medicare reimbursement for services performed by an outsourced therapy provider, the Secretary acts reasonably in estimating the overpayments based upon a statistical sample used by the Department of Justice to calculate the fraudulent billing in the criminal case against the therapy provider. Delaware Health apparently believes that by failing to maintain documentation to support hours billed to Medicare, it is absolved of any responsibility for improper reimbursement received due to the fraudulent conduct of the contractor it chose to provide services to Medicare beneficiaries in its facility. To the contrary,

the burden to produce auditable documentation for review to support Medicare billings always remains with the facility billing Medicare. See 42 C.F.R. §§ 413.20, 413.24. The intermediary could have removed all of the speech and occupational therapy billings because Delaware Health had no documentation to support the hours billed; instead, the intermediary took the less draconian approach of estimating the fraudulent billings by extrapolating the DOJ's statistical sample.

Although Delaware Health on its own became concerned about Whitehorse's billings for Medicare residents in 1998, there was virtually no testimony regarding any action Delaware Health took to reconcile those billings. A.R. 81-82, 88. Because of these concerns, however, Delaware Health refused to pay part of Whitehorse's bill. A.R. 82. Although Delaware Health's witness was unaware of whether Delaware Health's managers were advised of an investigation into Whitehorse, she was aware of some type of action against Whitehorse prior to the Intermediary's notice in August 2002. A.R. 88-89.

On August 21, 2002, the Intermediary, on behalf of CMS, advised the provider's administrator that upon review, it appeared that the provider reported inflated therapy costs for FY 1996 and 1997. A.R. 118. The intermediary expected to propose supplemental adjustments for those years. A.R. 118.

In determining whether the use of statistical extrapolation is permitted, courts generally look to whether a provider has been given the opportunity to challenge the findings based upon the extrapolation. See Ratanasen v. California Dep't. of Health Srvs., 11 F.3d 1467, 1473 (9th Cir. 1993) ("[C]ourts have approved the use of sampling and extrapolation on the condition that the party charged with overpayments has the opportunity to rebut the initial determination of

overpayments."); State of Georgia v. Califano, 446 F.Supp. 404 (N.D.Ga. 1977); Del Borrello v. Commonwealth Dep't. of Publ. Welfare, 96 Pa.Cmwlth. 507 (Pa. 1986); Oregon Mgmt.and Advocacy Center, Inc. v. Mental Health Div., Dep't. of Hum. Resources, 96 Or.App. 528 (Or. App.) rev. denied 308 Or. 405 (1989). Here, Delaware Health was afforded the opportunity both pre- and post-agency determination to challenge the findings; instead, Delaware Health sought to complain about the use of the statistic, rather than establishing in any way that its use was inaccurate. Given that the OIG and DOJ both used this statistic to calculate the level of fraudulent billing, the criminal perpetrator accepted the statistic, and the Intermediary received information that the fraudulent billing occurred throughout the period during which Whitehorse provided therapy and occurred at each of the providers it furnished services to (A.R. 140), it was incumbent upon Delaware Health to produce at least some indicia of inaccuracy if it sought to exclude the statistic and its extrapolation. See HCFA Ruling 86-1 (attached hereto as Exhibit 1), which states that the intermediary's sampling methodology is presumptively valid and the burden is on the provider to show otherwise. Delaware Health failed to produce even a scintilla of evidence as to any inaccuracy. It cannot now complain that the statistic was adopted. Delaware Health failed to meet its burden.

Delaware Health, at the administrative hearing, had a number of options to challenge the Intermediary's adjustments. Delaware Health could have produced the therapists who provided the services to challenge the Intermediary's finding that Whitehorse artificially increased the hours on the bills submitted. Delaware Health could have produced documentary evidence to challenge the Intermediary's finding that the logs were increased. Delaware Health could have conducted its own analysis to show that the statistic or the extrapolation were somehow

inaccurate. Instead, Delaware Health produced someone who oversees the bookkeepers (A.R. 76), and a statistician who barely skimmed over the Intermediary's documentation to support the adjustments in the case (A.R. 99), and could not definitively state that there was anything wrong with the extrapolation. A.R. 99 ("It may be accurate ..."). Delaware Health's expert testified that she only briefly reviewed the Intermediary's exhibits, and that her testimony was based only upon Delaware Health's exhibits. A.R. 98-99.

In a similar case, a healthcare provider sought to challenge the Secretary's extrapolation of a sample by producing an expert witness who criticized the statistical analysis upon which the Secretary based her Medicare recovery. Webb v. Shalala, 49 F.Supp.2d 1114, 1122-23 (W.D.Ark 1999). As in the case *sub judice*, the Secretary in Webb did not produce an expert witness to testify in support of the methodology used. Id. Nevertheless, the court recognized that the "methodology was developed by the U.S. Department of Commerce and refined for the specific purposes of the Medicare Program by the Department of Health and Human Services Inspector General's Office, Division of Program Audit." Id. Likewise, in this case, the methodology was developed by the U.S. Department of Justice (A.R. 140-146), and the Office of Inspector General conducted an investigation into the inflated costs. A.R. 133-134. Finding that "[t]he use of sampling and extrapolation as part of audits to determine overpayments to parties who receive publicly-funded reimbursements has been approved by courts in a number of settings," the court recognized that in similar situations, so long as the provider was afforded the opportunity to rebut the evidence, the Secretary could rely upon statistical samples and extrapolation. Id. at 1123; Ratanasen v. Calif. Dept. of Health Servs., 11 F.3d 1467 (9th Cir. 1993). The Secretary acted within his discretion in adopting the statistical sample from DOJ.

Before issuing the final notice, the Intermediary provided Delaware Health with the opportunity to dispute the findings upon which the extrapolation was based. A.R. 80, 120-124 Delaware Health chose not to provide the requested information.[6] A.R. 80. Additionally, Delaware Health's own witness admitted that to retrieve the necessary documentation "would have taken an enormous amount of work . . . I can't even imagine how much time and work that would have taken." Id. In any event, Delaware Health's witness conceded that any attempt to document the hours of therapy would be futile, because the notes only reflect that therapy was provided, not the length of the therapy:

> But it wouldn't have proved anything because they wrote in those notes that therapy services were provided. But they didn't say how long. So how would I know if they had three units that day, and they wrote in there that they gave Mrs. Smith this, and they did this with her, if it was 45 minutes or a half an hour? I would not have know, and I couldn't prove that unless, I guess, Mrs. Smith came along with it and said, well, on that day, at that time, I had a half an hour , or 45 minutes versus a half an hour.

A.R. 81.

In instances such as the case *sub judice*, it is incumbent upon the provider to produce documentation to support its claimed reimbursement. If Delaware Health sought to include the adjusted therapy hours, it should have produced evidence that the therapy occurred for the length

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[6]The Secretary here would have been justified in completely removing the entire disputed cost. See Girling Health Care, Inc. v. Shalala, 85 F.3d 211, 216 (5th Cir. 1996) (where the provider was unable to provide reconciliation for billing logs the court concluded that "[f]ailure to provide records susceptible of being audited allows the Secretary to deny reimbursement."). Here, the intermediary reasonably, and perhaps generously, only removed a portion of the cost identified by the extrapolation from the statistical sample, but identified the reason for removing the cost as the provider's failure to retain and make available to the intermediary at time of audit such records that adequately support cost data and cost finding. 42 C.F.R. §§ 413.20 and 413.24. A.R. 135-36.

of time it sought for reimbursement, or otherwise shown that the Intermediary's extrapolation actually resulted in some type of inaccuracy. Instead, Delaware Health attempted to improperly shift the burden to the Intermediary. In essence, Delaware Health attempted to force the intermediary to prove that the therapy did not occur, when the burden is on the provider to prove that it did occur for the length of time billed. Delaware Health submitted claims to Medicare for reimbursement from a contractor that was convicted of fraudulently inflating its therapy costs, and the Department of Justice's investigation revealed that the therapist engaged in the same fraudulent conduct at Delaware Health.

Notwithstanding this background, Delaware Health apparently believes that its payment of the therapy bills provides sufficient proof for reimbursement purposes. Evidently, seeking any further documentation to support these costs was too time consuming for Delaware Health. The Intermediary, however, could not simply ignore the fraud that was committed and admitted to in criminal court, and ignore the improper reimbursement paid, and therefore sought a reasonable means to calculate the billings attributed to the fraud committed, rather than simply removing the entire therapy cost from reimbursement. See Chaves Co. Home Health Serv. v. Sullivan, 931 F.2d 914, 918 (D.C. Cir. 1991) cert. denied 502 U.S. 1091 (1992) ("[T]he Secretary has the duty and power to protect against overpayments to providers."). When it provided its methodology to Delaware Health, Delaware Health found it unnecessary to suggest a different methodology or provide documentation to substantiate the cost, or even suggest that the methodology resulted in any inaccuracy. The Girling decision is particularly instructive: "The provider bears the burden of maintaining financial records and statistical data sufficient for proper determination of costs payable under the program." Girling, 85 F.3d at 215; 42 C.F.R. § 413.20(a). Thus, it was clearly

incumbent upon Delaware Health to produce documentation or other evidence as to the hours billed. CMS has an obligation to recover, and a commonlaw right to recoup, improper payments. See Mt. Sinai Hosp. of Greater Miami, Inc. v. Weinberger, 517 F.2d 329 (5th Cir. 1975), op. modified 522 F.2d 179, cert. denied, 425 U.S. 935 (1976).

In Illinois Physicians Union v. Miller, 675 F.2d 151 (7th Cir. 1982), where a healthcare provider challenged a state administrator's use of a statistical extrapolation to recover improper billings, the Seventh Circuit permitted the burden to rest with the provider to show entitlement to the billings. See also, Rutherford v. Michigan Dep't. of Social Serv., 483 N.W.2d 410 (Mich. Appeal 1991), appeal denied, 495 N.W.2d 387 (Mich. 1992), recons. denied, 497 N.W.2d 189 (Mich. 1993). The Miller court found this position consistent with, and controlled by, Lavine v. Milne, 424 U.S. 577 (1976). The court found that the provider could have produced evidence that the sample used was improper, or conduct a one-hundred percent audit of its own. The court further found nothing wrong with requiring the provider, rather than the state, be the party to bear the cost of an audit. Similarly, in Maryland Dep't. of Human Resources v. Dep't. of Health and Human Services, 762 F.2d 406, 408 (4th Cir. 1985), the Court found that the financial burden resulting from an improper disbursement of federal funds should not fall on the federal government. Instead, the equitable principles dictate that the disburser of the federal funds (i.e. Delaware Health), as the entity that could "best safeguard against erroneous payments," should bear the burden. Id. Finally, regarding challenges to government policies in the context of administering social welfare programs, the Supreme Court has stated: "The problems of government are practical ones and may justify, if they do not require, rough accommodations—illogical, it may be, and unscientific." Weinberger v. Salfi, 422 U.S. 749, 769

(1975) (quoting Metropolis Theatre Co. v. City of Chicago, 228 U.S. 61). Another court stated it this way: "It has been said that the true test for ascertaining the validity of a classification fashioned to control excessive costs under the Medicare program is whether it can be said that the Secretary could rationally have concluded both that a particular limitation or qualification would protect against (the potential abuse) and that the expense and other difficulties of individual determinations justified the inherent imprecision of a prophylactic rule protecting against such abuse." Fairfax Hosp. Ass., Inc. v. Califano, 585 F.2d 602 (4th Cir. 1978) (internal quotation omitted). Courts have placed the burden on providers (or those maintaining the records) to rebut the government's statistical sample. See State of Georgia v. Califano, 446 F.Supp. 404, 410 (N.D. Ga. 1977); Miller, 675 F.2d 151. In the case *sub judice*, Delaware Health has not even come close to meeting its burden in its attempt to have the statistical extrapolation thrown out—it did not conduct its own review to show that the extrapolation was invalid or that the results were incorrect, it did not suggest another method of determining the overpayment, nor did it produce any evidence that statistical sample was invalid, nor did it produce evidence to support its claimed costs. Therefore, Delaware Health has no basis to complain about the Secretary's use of the statistical extrapolation in this case.

The Secretary can reasonably rely upon the statistical sampling by a Department of Justice auditor, particularly in an instance such as this where the sample used resulted in the successful criminal conviction of the persons actually committing the wrong-doing and restitution orders.[7] Delaware Health was given the opportunity both prior to the Intermediary

[7]Although research has not uncovered another case with the exact facts of this case, Plaintiff's arguments are the same that have always been leveled at the Secretary: the specific improper payments of the sample are unrelated to the extrapolation. Plaintiffs invariably argue

issuing the NPR and at its PRRB hearing, to challenge these findings. It failed to do so. Additionally, collateral estoppel prevents those, such as Delaware Health, who are in privity with the criminal actor from re-litigating in a separate action facts and law that were decided in the criminal case. See Alt v. C.I.R., 1994 WL 320823 (U.S. Tax Ct. 1994); Montana v. U.S., 440 U.S. 147, 153 (1979). The Administrator's decision emphasized that "factual findings in the criminal matter that this same pattern of fraud occurred at the Provider involving the same criminal defendants need not be readjudicated in this administrative case ... and those findings are herein adopted." A.R. 6; see Maietta v. Artuz, 84 F.3d 100, 103 n.1 (2d Cir.) cert. denied 519 U.S. 964 (1996) ("Application of collateral estoppel from a criminal proceeding to a subsequent civil proceeding is not in doubt. It is well-settled that a criminal conviction, whether by jury verdict or guilty plea, constitutes estoppel in favor of the United States in a subsequent civil proceeding as to those matters determined by the judgment in the criminal case.") (internal quotations omitted).

Delaware Health had the opportunity to establish that the statistical sample used in this instance was invalid, but failed to do so. Furthermore, Delaware Health submitted no proof regarding any differences between itself and the other SNFs who had been defrauded, to justify exclusion of the extrapolation. There was no evidence that the patient population at one SNF (i.e. Harrison House of Georgetown) receiving therapy by Whitehorse differed in any meaningful way from Delaware Health's patient population (or any other SNF population); nor any basis to conclude contrary to the Intermediary's evidence that Whitehorse committed the same fraud at

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that either the statistical sample is improper or Secretary cannot rely upon an extrapolation of the sample, because it does not uncover the exact wrongdoing of each individual payment. These arguments fail, and should fail in this case as well.

Delaware Health that it committed at Harrison House of Georgetown (A.R. 140); nor any evidence to conclude that the fraud was committed in a different proportion at Delaware Health than it had been committed at Harrison House of Georgetown; nor did Delaware Health produce evidence that it had some heightened mechanism in place during the audit period to detect fraud by Whitehorse on any greater scale than Harrison House of Georgetown had in place, or at all; nor did it produce any evidence to support the hours that it billed Medicare for therapy services.[8] Thus, while Delaware Health had the opportunity to present such evidence at the hearing, it chose not to, and instead appeared to disbelieve that such fraud could have been committed by its therapy contractor. In a case where a provider argued that the Intermediary's calculation of its reimbursement was inaccurate due to documented fraudulent claims processing by the Intermediary, the court nonetheless found that the Department's use of the Intermediary's results were justified. See Campbell's Personal Care v. Thompson, 258 F.Supp.2d 846, 850 (N.D. Ill. 2003).

Aside from criticizing the Intermediary's use of the DOJ statistic by claiming insufficient evidence to determine whether it was valid, Delaware Health offered no sampling method of its own to utilize. Instead, Delaware Health either feigned lack of knowledge of fraud committed, or claimed that its own records, which it stated were too voluminous to review in the aggregate, would show no evidence of the fraudulent billing. In light of the fact that Delaware Health could offer no other method to account for the fraud, either when given the chance to do so by the Intermediary before the cost settlement was finalized, or at the evidentiary hearing after it had been finalized, the Intermediary's use of the DOJ statistic makes sense. In Ratanasan, supra, the

[8]Of course Delaware Health's testimony adduced that no such time records even existed.

Medi-Cal program offered the provider from whom it sought to recover an overpayment due to fraudulent billing the opportunity to participate in an exit interview, which "would have afforded the [provider] the opportunity to rebut the initial determination of overpayments." 11 F.3d at 1472. The provider in that case, however, did not participate and the State went forward with the audit findings. In the case *sub judice*, the Intermediary offered Delaware Health the opportunity to respond to the Intermediary's proposed findings and submit documentation/information, before the Intermediary issued the final agency notice. A.R. 120-121. Delaware Health chose not to do so. Likewise, the Intermediary here reasonably went forward with the unrebutted audit findings based upon the extrapolated sample. The government has "an interest in minimizing administrative burdens." Yorktown Medical Lab., Inc. v. Perales, 948 F.2d 84, 90 (2d Cir. 1991).

Delaware Health also criticized the Intermediary for extrapolating Whitehorse's fraudulent billing at Delaware Health based upon Whitehorse's fraudulent billing at Harrison House of Georgetown. However, as noted above, Delaware Health produced no evidence that there was anything improper or unreliable in doing this. Whitehorse provided therapy services to both Delaware Health and Harrison House during the same period, and the criminal investigation uncovered that Whitehorse padded the hours it submitted on its bills, and increased the hours on its therapists logs by fraudulently altering the hours to higher numbers.

Although Delaware Health chose and contracted with Whitehorse to provide therapy services to its residents, Delaware Health attempts to pass the liability onto the Medicare Program for the fraud Whitehorse committed to Delaware Health. Perhaps even more egregious, however, is Delaware Health's turning a blind eye to the fraudulent billing that has been

committed and its own attempt to pass on that fraudulent billing to Medicare in an attempt to have the taxpayers reimburse for services never provided to Medicare beneficiaries. The record is devoid of any evidence of investigation conducted by Delaware Health after its own concern of billings in 1998 by Whitehorse, and even after being advised that this activity occurred.[9] Delaware Health appears to bury its head in the sand to the knowledge that two principles from Whitehorse have admitted to fraudulently billing for services not provided, have pled guilty to the crime and one of whom has served a prison sentence. Medicare should not bear the cost when a provider pays for services not performed.

In sum, Delaware Health has failed to meet its burden because it has not shown that the sample was not randomly chosen, nor that the sample or extrapolation were unreliable. Moreover, because Delaware Health was in a better position than the Intermediary to obtain documentation to uncover the fraudulent conduct, or to produce witnesses to testify that the therapy was provided as billed, Delaware Health could have conducted its own audit to show that the Intermediary's method was improper. Delaware Health did none of these things, however, and thus has failed to carry it burden in this case to show it is entitled to the disputed reimbursement.

C. The Provider Failed to Meet its Burden to Substantiate the Hours it Sought for Reimbursement.

The burden is on the provider to establish that costs it seeks for reimbursement are proper. Medicare regulations make it clear that the provider must maintain adequate

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[9]There is virtually no testimony regarding steps Delaware Health took when, on its own, it began to suspect improper billing by Whitehorse. See A.R. 81-82, 88.

documentation to support its claimed costs.[10] See 42 C.F.R. § 413.20 ("The principles of cost reimbursement require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program."); § 413. 24(a) ("Provider receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors."); § 413.24(c) ("Adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended."). Delaware Health did not maintain adequate data. It had bills which it paid to its contractor, but did not have the actual records documenting the length of time for each visit the therapist allegedly worked with the beneficiary. In order to support these claimed costs, Delaware Health should have maintained records documenting the length of time of each visit, as Delaware Health's claim to the Intermediary was based on a length of time, and not just a bill for a service.

Plaintiff appears to argue that the Intermediary needed to produce testimony—evidence to support its use of the statistical analysis. However, as this is an administrative proceeding, with relaxed evidentiary standards, the Intermediary need not adduce testimony—it may establish the practicality/reliability of it sample through other evidentiary means—such as the introduction of exhibits and hearsay, which it did. There was evidence to establish how the sample was derived, why that method was used, why it was the best method available, how and why the sample was

[10]The Intermediary identified these regulations (42 C.F.R §§ 413.20 and 413.24) as the basis for the adjustments to the NPR. A.R. 135-36.

applied to Delaware Health. The Provider had ample opportunity to produce evidence that the sample was inappropriate, that another method could have been chosen, it chose not to do any of this.

Plaintiff, before the Administrator, proffered four cases to support its position that the Intermediary's use of the statistical extrapolation was inappropriate. Upon review, none of the cases help the Plaintiff. Hosp. San Francisco, Inc. v. Cooperativa de Seguros de Vida de Puerto Rico, PRRB Dec. No. 2003-D57, a decision by the PRRB[11] cited by Plaintiff, was reviewed by the Administrator, who reversed the PRRB's denial of the use of the statistical extrapolation, thus supporting the Secretary's position in this case. See Hosp. San Francisco, Inc. v. Cooperativa de Seguros de Vida de Puerto Rico, 2003 WL 23111373 (HCFA Adm. Dec. November 10, 2003). Likewise, in Providence Medical Center v. Blue Cross and Blue Shield Assoc., CCH Medicare and Medicaid Guide ¶ 80,175 (HCFA Administrator Dec. March 13, 1999), the Administrator reviewed and reversed the decision of the PRRB, thereby approving the use of statistical sampling. Earlier in this brief, the Secretary set out how Webb v. Shalala, 49 F.Supp.2d 1114 (W.D. Ark. 1999), supports the Secretary's decision in this case. Finally, County of Los Angeles v. Shalala, 192 F.3d 1005 (D.C. Cir. 1999), cert. denied, 530 U.S. 1204 (2000), is inapposite to the facts in this case. There, the Court remanded the case, finding the Secretary was arbitrary and capricious by explicitly ignoring data without any explanation. Such is not the case here. In the case *sub judice*, there was no contradictory data. The only information available was that the sub-contractor inflated its costs and the proportion of costs

[11]Citing PRRB decisions to the Secretary is of limited value as PRRB decisions are not binding on the Secretary. Comm. Care Found. v. Thompson, 318 F.3d 219, 226-27 (D.C. Cir. 2003).

inflated. No contrary or contradictory evidence was presented.

D. The Secretary May Proceed to Recover a Medicare Overpayment Against a Provider, Even Where the Criminal Court Has Ordered Restitution by the Criminal Actors.

It was asserted that the criminal court's order of restitution to the criminal defendants, who were not parties in this administrative action, precludes the Secretary from making a claim for reimbursement from the provider for improper Medicare payments. This argument is fallacious and should fail. This provider sought Medicare reimbursement, submitted claims to Medicare for reimbursement, and Delaware Health actually received Medicare reimbursement for services that were never provided to Medicare beneficiaries. The Secretary can, and must, seek recovery of improper reimbursement from a Provider who received the improper reimbursement and submitted improper claims. The order of restitution to other criminals does not obviate the provider's responsibility to return improper reimbursement. See, e.g., Mitchell v. Johanns, 400 F. Supp.2d 1133 (S.D. Iowa 2005). The Provider was in the best position to protect itself from the fraudulent conduct, was the entity that failed to implement any oversight of its own sub-contractor, and is the one who obtained the reimbursement from the Secretary for services not provided. Although Delaware Health may not be as culpable in the scheme to defraud Medicare as those criminally responsible, it nonetheless remains a party responsible for submitting improper claims and obtaining improper reimbursement.

CMS's regulation provides that CMS need not proceed against only one debtor, but may proceed against any and all debtors. See 42 C.F.R. § 401.623. Although the Secretary agrees that he may not seek a double recovery of the improper payments, this does not prevent the Secretary from seeking recovery against all parties responsible for reimbursing the overpayments.

See, Creel v. Comm'r of Internal Revenue, 419 F.3d 1135, 1140 (11th Cir. 2005) ("[T]he restitution statute ... expressly contemplates that a civil claim may be brought subsequent to a criminal conviction by providing for an offset for the amount of restitution paid in the criminal case against any damages recovered in the civil proceeding.") To the extent that the Secretary obtains any recovery from the criminal actors for any of their fraudulent services to Delaware Health (presumably after they obtain employment after they are released from incarceration), Delaware Health's financial obligation to the Secretary can be reduced by a corresponding amount. See, e.g., U.S. v. Bright, 353 F.3d 1114 (9th Cir. 2004). The provider's right to seek contribution from the criminal actors and its right to reduce its obligation by any recovery obtained from the criminal actors, however, does not prevent the Secretary from obtaining a recovery from Plaintiff.

E. Notwithstanding that the Purported Standards were Inapplicable to this Situation, the Intermediary Nonetheless Met the Auditing Standards.

Delaware Health introduced excerpts of the PRM and General Accounting Standards, as standards that must be adhered to when the government utilizes sampling. A.R. 95, 206, 207-30. However, handbooks, manuals and guidelines do not have the authority of regulations, are not binding, and lack the force of law. Schweiker v. Hansen, 450 U.S. 785, 789, reh'g denied, 451 U.S. 1032 (1981); Pub. Citizen, Inc. v. U.S. Dept. of Health & Human Servs., 332 F.3d 654, 660 (D.C. Cir. 2003); Christensen v. Harris County, 529 U.S. 576, 587 (2000). Delaware Health's expert witness testified that she could not tell, based upon the information provided to her, whether the Intermediary had followed General Accounting Principles. A.R. 95. Notwithstanding the expert's inability to determine whether standards were met, the Supreme

Court has held that the Secretary is not required to follow generally accepted accounting principles in administering the Medicare program. See Shalala v. Guernsey Mem. Hosp., 514 U.S. 87 (1995). More importantly, however, Delaware Health's expert conceded that there are times when a non-statistical sample is justified. A.R. 95-96. She further conceded that there are times when it is justified to extrapolate based upon the records of another provider. A.R. 97-98. Notwithstanding the provider's expert's inability to agree that extrapolation based on another provider's statistical sample should have been utilized in this case, it was nonetheless a reasonable act of discretion for the Secretary to make that determination based on the facts of this case.

Delaware Health sought to apply standards to the Intermediary's use of a DOJ statistic that the Intermediary was not required to meet. The Intermediary conducted no "audit" in this case; the Intermediary performed a desk review, which is not subject to the same requirements.[12] See, e.g., A.R. 209, 217 ("The Medicare cost report is always desk reviewed and about one-third are audited."). Delaware Health's own exhibit (Ex. P-7) establishes that many requirements do not apply to "no-audits" and "reopenings." A.R. 217. Moreover, that same exhibit recommends that the Intermediary "consider other audits of the provider which may have an effect upon the cost report." A.R. 209. Additionally, "[i]f the other audit work is required to be performed under standards required for Medicare purposes, quality is assumed..." A.R. 209. Medicare's Manual regarding the Intermediary's use of other audits states:

> Determine the extent, if any, to which you may rely on other audit work. In making this determination, consider the general nature of the other audit's objective...

[12]An audit, if it occurs at all, happens after a desk review. A.R. 209.

A.R. 209. The Manual expects the intermediary to consider audits conducted by and for other government programs. "By relying on other auditors' work, you can avoid duplication of audit work..." A.R. 209. The Intermediary's use of DOJ's statistic to estimate the fraudulent billings by Delaware Health's sub-contractor was both reasonable, and consistent with Medicare's own manual for reviewing cost reports and making adjustments, even though the Intermediary was not required to meet those standards in this case. There was no need to duplicate or verify work that had been conducted by the DOJ during the course of the criminal prosecution of the fraudulent biller. Delaware Health, however, was free to present any evidence which would tend to show that these statistics were invalid; it failed to do so. Consistent with earlier arguments, the Manual provision admonishes the Intermediary to "[a]djust any amounts not adequately documented." A.R. 218. Therefore, it was incumbent upon the Intermediary, when faced with DOJ statistics estimating the extent of the fraud committed, coupled with Delaware Health's inability to verify the time periods billed, to adjust the cost report to remove fraudulent billings. Thus, even if the Intermediary were to be held to auditing standards for this desk review reopening, the Intermediary complied with the applicable standards.

Delaware Health pointed to Exh. P-8 before the PRRB as setting standards for the Intermediary. However, that exhibit applies to "Field Work Standards for Performance Audits." A.R. 222. There is no evidence that these standards apply in this situation–the Intermediary did not conduct a field audit here, and there is no evidence that there was a "performance audit." Thus, these standards are inapposite.[13] However, even those standards recognize that "[e]vidence

[13]Delaware Health's Exh. P-8 identifies itself as Chapter 7 of the GAS; however, the Intermediary Manual (CMS Pub. 13-4) § 4112, entitled Standards For Audit Under Medicare

obtained from a credible third party may in some cases be more competent than that secured from management or other officials of the audited entity." A.R. 223. That section of the Government Auditing Standards permits an auditor to include as evidence data from third parties. A.R. 225 and 226. These standards recognize that "[u]nderlying GAGAS audits is the premise that federal, state, and local governments and other organizations cooperate in auditing programs of common interest so that the auditors may use others' work and avoid duplication of effort." A.R. 230. Thus, the Manual provisions and General Accounting Standards support the Intermediary's use of the DOJ statistical extrapolation under the facts of this case.

CONCLUSION

For the reasons set forth above, the Secretary respectfully requests that his motion for summary judgment be granted.

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Respectfully submitted,

COLM F. CONNOLLY
United States Attorney

BY: _____
Lesley F. Wolf
Assistant United States Attorney
1007 Orange Street, Suite 700
Wilmington, Delaware 19899-2046
(302) 573-6277
lesley.wolf@usdoj.gov

(Exh. P-7, A.R. 206), states that audits of Medicare cost reports are government by Chapters 3, 4, and 5 of the GAS, with no mention that Chapter 7 applies. A.R. 206.

Brett Bierer
U.S. Department of Health and Human Services
Office of the General Counsel
Centers for Medicare & Medicaid Services Division
Room C2-05-23
7500 Security Boulevard
Baltimore, Maryland 21244-1850
(410) 786-1473
brett.bierer@hhs.gov

OF COUNSEL:

THOMAS R. BARKER
Acting General Counsel

JANICE L. HOFFMAN
Associate General Counsel

MARK D. POLSTON
Deputy Associate General
Counsel for Litigation

United States Department of
Health and Human Services

EXHIBIT 1

HCFA-CMS Rulings
HCFAR USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENTS TO PROVIDERS AND SUPPLIERS

HCFAR USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENTS TO PROVIDERS AND SUPPLIERS

Feb 20, 1986

MEDICARE PROGRAM

Hospital Insurance and Supplementary Medical Insurance Benefits (Parts A and B)

HCFAR USE OF STATISTICAL SAMPLING TO PROJECT OVERPAYMENTS TO PROVIDERS AND SUPPLIERS

HCFAR 86-1

Purpose: HCFA and its Medicare contractors may use statistical sampling to project overpayments to providers and suppliers when claims are voluminous and reflect a pattern of erroneous billing or overutilization and when a case-by-case review is not administratively feasible.

Citations: 1815(a), 1842(a), and 1861(v)(1)(A)(ii) (42 U.S.C. 1395g(a), 1395u(a), and 1395x(v)(1)(A)(ii)); 42 CFR 401.108.

Pertinent History: The provider billed and was paid by Medicare for services to beneficiaries from September 1982 through July 1985. As result of a subsequent audit of the provider's Medicare claims, the intermediary discovered a large number of bills for medically unnecessary services. The intermediary also determined that the provider knew or should have known that the services were not covered and, therefore, was not entitled to have payment made to it for the services.

The intermediary considered conducting a case-by-case review in order to determine the amount the provider had been overpaid for the services. This would have entailed an examination of all of the provider's beneficiary records for the period in question in order to identify those beneficiaries who had received unnecessary services. It also would have been necessary to tabulate the total amount that Medicare had paid the provider for each beneficiary. The intermediary decided that this method of determining the amount of the overpayment was not administratively feasible, given the volume of records involved and the cost of retrieving and reviewing all the beneficiary records for the period in question. The cost of identifying and calculating each individual overpayment itself would constitute a substantial portion of the amount the intermediary might reasonably be expected to recover. Further, the allocation of sufficient staff to reexamine all individual claims for the period in question would interfere with current claims processing activities to an unacceptable degree.

The intermediary notified the provider that, because of the volume of records and the costs of retrieving and reviewing all records for the period as discussed above, it intended to project the overpayment by reviewing a statistically valid sample of beneficiary records and that if it were determined that the provider had been overpaid for the sample cases, it would project the results (again using statistically valid methods) to the entire population of cases from which the sample had been drawn. This would result in a statistically accurate estimate of the total amount the provider had been overpaid for services to these beneficiaries.

The provider objected to the intermediary's use of sampling to project the overpayment on the following grounds:

1. There is no legal authority in the Medicare statute or regulations for HCFA or its intermediaries to determine overpayments by projecting the findings of a sample of specific claims onto a universe of unspecified beneficiaries and claims.

2. Section 1879 of the Social Security Act, 42 U.S.C. 1395pp, contemplates that medical necessity and custodial care coverage determinations will be made only by means of a case-by-case review.

3. When sampling is used, providers are not able to bill individual beneficiaries not in the sample group for the services determined to be noncovered.

4. Use of a sampling procedure violates the rights of providers to appeal adverse determinations.

5. The use of sampling and extrapolation to determine overpayments deprives the provider of due process.

(The succeeding presentation of our decision and supporting facts is applicable also to the use of sampling to project overpayments to suppliers (including physicians) whose claims are processed by Medicare carriers when 100 percent readjudication would be excessively costly or impractical.)

The Supreme Court has long recognized that the Federal Government possesses an inherent right to recover monies illegally or erroneously paid out. United States v. Carr, 132 U.S. 644, 650 (1890); Wisconcin Cent. R.R. v. United States, 164 U.S. 190, 212 (1896). This right exists independent of statute. See United States v. Wurts, 303 U.S. 414, 416 (1938); Grand Trunk W. Ry. v. United States, 252 U.S. 112, 121 (1920). The Government may enforce its rights of recoupment by reasonable means, and it may exercise that right without resorting to litigation by offsetting the amount against sums otherwise due. United States v. Munsey Trust Co., 332 U.S. 234, 239-240 (1947). Offsets against current or subsequent obligations may be used to prevent a recipient of Federal funds from retaining monies that are later found to have been unauthorized by the terms and conditions under which they were received. Wisconsin Cent. R.R. v. United States, supra, 164 U.S. at 211-212.

The Government's common law right of recoupment, and its corollary power of recovery by offset, are based on strong considerations of public policy. All funds at the disposal of the Government belong to the public. As custodian of these funds, a Federal agency has the fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. Accordingly, if the public's money has been expended in a manner not authorized by statute, the agency's obligation requires it to take administrative actions necessary to prevent an unjust enrichment by the recipient at the expense of the Federal treasury. See United States v. Wurts, supra, 303 U.S. at 415-416; Grand Trunk W. Ry. v. United States, supra, 252 U.S. at 120-121.

The common law right to recover Federal funds has been specifically recognized as being fully applicable to the Medicare program. Mt. Sinai Hospital v. Weinberger, 517 F.2d 329 (5th Cir. 1975); Wilson Clinic and Hospital, Inc. v. Blue Cross, 494 F. 2d 50 (4th Cir. 1974). Moreover, the courts have also recognized that extrapolation based on a sample is a valid audit technique in cases arising under the Social Security Act. Illinois Physicians Union v. Miller, 675 F. 2d 151 (7th Cir. 1982); State of Georgia v. Califano, 446 F. Supp. 404 (N.D. Ga. 1977); New Jersey Welfare Rights Organization v. Cahill, 349 F. Supp. 501 (D.N.J. 1972); Rosado v. Wyman, 322 F. Supp. 1173 (E.D. N.Y. 1970), aff'd 402 U.S. 991 (1971). In view of the enormous logistical problems in determining massive overpayments in social welfare programs, sampling is the only feasible method available. State of Georgia v. Califano, supra; Illinois Physicians Union v. Miller, supra.

Congress has affirmed the Government's right to recover Medicare Trust Funds by reasonable means from those who have no right to retain them. Section 1815(a) of the Social Security Act, 42 U.S.C. 1395g(a), authorizes "necessary adjustments on account of previously made overpayments or underpayments" under Medicare Part A. Similarly, as to Part B of Medicare, section 1842(a), 42 U.S.C.

1395u(a), provides that carriers make determinations as to the amount of payments to be made to providers of services and other persons, and authorizes such audits of the records as may be necessary to assure that proper payments are made. In addition, section 1861(v)(1)(A)(ii) of the Act, 42 U.S.C. 1395x(v)(1)(A)(ii), provides for the "making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive." These statutory requirements, in effect, would be abrogated if sampling were not available to determine Medicare overpayments. The imposition of such a result would be inconsistent with the settled principle that, when Congress creates a statutory right, the existence of appropriate remedies to enforce that right will be presumed in the absence of a clear indication of a contrary congressional intent. Texas & N.O.R.R. v. Brotherhood of Railway & Steamship Clerks, 281 U.S. 548, 569-570 (1939); Sullivan v. Little Hunting Park, Inc., 396 U.S. 229, 239 (1969).

Since HCFA's contractors process vast numbers of Medicare claims (for example, in fiscal year 1985, intermediaries received over 59.5 million Medicare claims and carriers received over 270.8 million claims), an interpretation that title XVIII of the Act mandates that a 100 percent review of cases be conducted before HCFA or its contractors can determine that providers or suppliers have been overpaid would make it virtually impossible for HCFA to implement these statutory provisions in many cases. A case-by-case review could require a significant diversion of staff from the ongoing claims process, and the cost of determining the amount of an overpayment would be prohibitively high unless a sampling method were used. To fulfill the congressional intent, HCFA must adopt realistic and practical auditing procedures. The alternative is to conclude that the intent of Congress was that, if case-by-case overpayment determinations are not administratively feasible, the Medicare Trust Funds must forego restitution of funds improperly obtained by providers and suppliers. We do not believe that was Congress' intent.

We also do not believe that the statutory provisions limiting provider or beneficiary liability preclude the use of sampling. In instances where Medicare coverage is denied because items or services furnished are not "medically necessary" or constitute "custodial" care, section 1879 of the Act, 42 U.S.C. 1395pp (42 CFR 405.330), authorizes a limitation of the beneficiary's liability when the beneficiary did not know, and could not reasonably be expected to have known, that the items or services were not "medically necessary" or that they constituted "custodial" care. The Medicare program will make payments to the provider when both the beneficiary and the provider were without the requisite knowledge. When the beneficiary did not have such knowledge, but the provider did, liability for the denied services rests with the provider and the beneficiary's liability is waived. The beneficiary will be indemnified by the Medicare program if he or she has already paid the provider. See 42 U.S.C. 1395pp. Liability will rest with the beneficiary only when he or she knew or could have been expected to know that the items or services furnished were not "medically necessary" or were "custodial" in nature.

The use of sampling to determine overpayments for medically unnecessary services or custodial care does not deprive a provider of its right to bill those beneficiaries who knew or should have known that they were receiving these services. Under the governing regulation, 42 CFR 405.334, a beneficiary is presumed not to have had such knowledge unless he or she was notified in writing by the provider, the intermediary, or the Peer Review Organization (PRO). For example, when a beneficiary who is receiving a course of treatment has received a previous denial notice stating that similar items or services were not covered, the previous denial notice would constitute evidence that the beneficiary did or should have had knowledge of noncoverage. See 42 CFR 405.334 for examples of acceptable written notice to a beneficiary. The operation of this provision effectively serves to resolve most limitation of liability questions in the beneficiary's favor. However, a provider that wishes to bill individual beneficiaries not included in the sample can identify those individuals who were previously informed that they were receiving noncovered services by inquiring of the intermediary or PRO as to whether it sent a notice to the individual. (The provider presumably did not give notice to the beneficiary that the services were not covered because, if it had, it is unlikely that it would have billed Medicare for the services.)

Even if we assume that a provider is effectively precluded from billing a beneficiary in certain cases, this assumption would not bar the Government from its fundamental obligation to ensure that Federal funds are spent only for those purposes permitted by law. As between the provider and the Government, strong

considerations of public policy favor recovery. On the other hand, the provider had the responsibility to know and should have known that the services furnished were not medically necessary. Moreover, as the United States Court of Appeals for the Fifth Circuit recognized in Mt. Sinai Hospital of Greater Miami v. Weinberger, 517 F. 2d 329 (5th Cir. 1976), the provider assumes substantial responsibility for overpayments.

... the hospital is not a neutral, innocent party in this three-way transaction between HEW, Medicare beneficiary and Medicare provider. The decision to provide a service is made by the individual attending physician, who is far better informed on both the medical issue and the scope of Medicare coverage than is the patient-beneficiary. The physician is either an employee of the hospital or a doctor with staff privileges. Whatever else the granting of staff privileges may connote, it is clear to us that it involves a delegation by the hospital of authority to make decisions on utilization of its facilities. 534 F. 2d at 338.

In reimbursing providers, HCFA has to balance the need to process billings rapidly in order that a provider's liquidity needs do not suffer and the need to verify that the claims submitted are for services covered by the Act. Mixed into this balance is the volume of claims which must be reviewed. Considering the volume of claims (as cited earlier to be over 330.3 million for fiscal year 1985), it is virtually impossible to examine each bill submitted by a provider or supplier in sufficient detail to assure before payment in every case that only medically necessary services have been provided. Therefore, as a practical matter, HCFA and its contractors must depend on the provider to submit claims for services that are covered by the Act. In most cases, this reliance is justified. However, if HCFA or its contractors later have reason to make an indepth and careful review of claims for services which had been previously paid and discover that medically unnecessary services have been provided, a provider cannot cry "foul" when these payments (to which they were never legally entitled) are recovered.

Sampling does not deprive a provider of its right to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

The provisions of the statutes and regulations provide a constitutionally sufficient means by which the provider may challenge an overpayment determination. In cases of denials made through sampling which are based on medical necessity or custodial care, section 1879 of the Act, 42 U.S.C. 1395pp, permits the provider to assert the same appeal rights that an individual has under the statute when the individual does not exercise his rights to appeal. Under Part A, these rights include an opportunity for reconsideration (42 CFR 405.710-405.716), an oral evidentiary hearing by an administrative law judge (42 CFR 405.720-405.722), Appeals Council review (42 CFR 405.701(c) and 405.724), and finally judicial review if the amount in controversy is $1,000 or more (42 CFR 405.730; 42 U.S.C. 1395ff(b)(2)). In cases that do not involve medical necessity or custodial care, 42 CFR 405.370, et seq. sets out the applicable procedures through which current payments may be suspended (offset) to recover an overpayment under the Medicare program. Under 42 CFR 405.371, a provider is given notice as to the basis for the overpayment and an opportunity to respond before an intermediary may suspende current Medicare reimbursement. 42 CFR 405.372, in conjunction with 42 CFR 405.370(b), forestalls any suspension pending consideration of any statement by the provider in opposition to the notice of suspension. Finally, if it is determined that a suspension should go into effect, written notice of the determination will be sent to the provider or other supplier. The notice will contain specific findings on the conditions upon which the suspension was based and an explanatory statement for the final decision. Thus the administrative scheme provides sufficient means for a provider to challenge overpayment determinations that are made on the basis of sampling.

Under Part B, suppliers who accept assignment may request a Medicare carrier to review a payment

determination with which the supplier disagrees (42 CFR 405.807). If the supplier is dissatisfied with the carrier's review determination, the supplier may request a hearing before a carrier hearing officer if the amount in controversy is $100 or more (42 CFR 405.820). There are no further appeals available under Part B. In U.S. v. Erika, Inc., 456 U.S. 201 (1982), the Supreme Court ruled unanimously that, under current law, the Part B hearing is rightfully the final step in the Part B appeals process.

In summary, the use of sampling is a reasonable and cost effective method of projecting overpayments under Medicare. It is not unfair to a provider or supplier to hold it accountable for the receipt of Medicare funds to which it is not entitled under the statute. To the contrary, allowing a provider or supplier improperly to retain large sums of program funds would be unfair to the intended beneficiaries of Medicare and to the taxpayers who contribute to the trust funds. As the Supreme Court held in Richardson v. Perales, 402 U.S. 389 (1971), the system must not only be fair, but it must work.

Ruling: Accordingly, it is held that the use of statistical sampling to project an overpayment is consistent with the Government's common law right to recover overpayments, the Medicare statute, and the Department's regulations, and does not deny a provider or supplier due process. Neither the statute nor regulations require that a case-by-case review be conducted in order to determine that a provider or supplier has been overpaid and to determine the amount of overpayment.

Effective date: This Ruling is effective February 20, 1986.